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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,546	05/02/2002	Dan L. Eaton	P3230R1C001-168	1060

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/063,546	EATON ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

RESPONSE TO AMENDMENT

The amendment and response filed 10-26-06 has been entered into the record. Claim 6 has been cancelled. Claims 1-5 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Withdrawn

The rejection of claims 1-5 under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial and credible utility or, in the alternative a well-established utility is withdrawn for reasons set forth below.

The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention is withdrawn for reasons set forth below.

Applicants' response states that the gene expression data in the specification, Example 18, shows that the mRNA associated with the polypeptide was more highly expressed in normal tissue as compared to tumor tissue. Gene expression was analyzed using standard semi-quantitative PCR amplification reactions of cDNA libraries isolated from different human tumor and normal human tissue samples. Identification of the differential expression of the polypeptide-encoding gene in tumor tissue compared to the corresponding normal tissue renders the molecule per se and antibodies that specifically

bind the molecule useful and enabled as a diagnostic tool for the determination of the presence or tumor.

Example 18 at page 140 of the instant specification demonstrates differential expression of DNA58723-1588 qualitative PCR amplification reactions. DNA58723-1588 to be more highly expressed in normal skin as compared to the corresponding melanoma tumor in this Example. Applicant states in the response that Example 18 utilizes a more accurate and reliable method of assessing changes in mRNA levels, namely quantitative PCR analysis. Applicant relies on more than 100 references, where expression levels of mRNA, measured by quantitative PCR, were found to have a good correlation to the expressed protein levels.

It had been previously argued in the office actions of record that mRNA levels were not predictive of protein levels, citing several references including Haynes et al, Gygi et al and Chen et al. However, these references were measuring and analyzing mRNA levels using microarrays, not using quantitative PCR analysis and the art recognizes the results obtained by microarray are not always the same as the results obtained using quantitative PCR (for example see Oda et al. Virchows. Arch. 430:99-105, 1997, specifically page 104, column 1, paragraph 2). While the PTO found several references in which the protein expression levels did not correlate with mRNA levels measured by quantitative PCR (see Sugg et al, Clinical Endocriniology 49:629-637, 1998; Toler et al. Am. J. Obstet. Gynecol. 194:e27-231, 2006; Berner et al Histopathol 42:546-554, 2003; Brooks et al Am. J. Renal Physiol 284:F218-F228, 2003), the majority of the references which were found, including those cited by Applicant, demonstrated a correlation between mRNA levels measured by quantitative PCR and protein expression levels.

Applicant asserts that the expression levels of protein correlate to mRNA (cDNA) levels when the cDNA is measured by quantitative PCR (i.e. rt-PCR). Applicant has provided more than 100 references in support of this position. The prior art of record (Haynes et al, Gygi et al, Chen et al.) argued by the Examiner, is not specifically directed

to message levels measured by rt-PCR. Based on the totality of evidence of record, one of skill in the art would find it more likely than not that an increase in message as measured by rt-PCR would be predictive of an increase in protein expression levels, absence evidence to the contrary. Therefore, the data presented in Example 18, which demonstrates differential expression of nucleic acids encoding the polypeptide, also supports a conclusion of differential expression of the polypeptide. Therefore, one of ordinary skill in the art would be able to use the antibodies that specifically bind the polypeptide diagnostically for distinguishing tumor from normal tissue as asserted by Applicant.

New Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Barnes (WO 00/18904, published 06 April 2000).

Barnes teaches murine TANGO 215 that is 91.3% identical as compared with SEQ ID NO:38 (see Figure 56 of Barnes). Barnes teaches antibodies, polyclonal, monoclonal, chimeric and humanized and fragments thereof that bind the murine TANGO 215 polypeptide (see page 71, lines 9-15; page 72, lines 12-20; page 75, lines 3-8). Barnes teaches labeled antibodies at pages 75-76 and 109-110). Barnes et al teach that antibodies can be made to any antigenic peptide of a protein of the invention that comprises at least 8, 10, 15, 20 or 30 amino acid residues of the sequences. As such, since

the sequences have long stretches of 100% identical regions as compared to SEQ ID NO:38, the antibodies of the prior art would necessarily and inherently bind the instantly claimed SEQ ID NO:38. As such, the claims are anticipated.

It is noted that the rejection of record has been converted to a 102(a) in view of the new priority date.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to an antibody fragment. Since all antibody fragments do not have to specifically bind to the polypeptide of SEQ ID NO:38, it is unclear as to what applicants intend by this language. Amendment of the claim to an independent claim such as "An isolated antibody fragment that specifically binds to the polypeptide of SEQ ID NO:38" would obviate this issue.

Status of Claims

Claims 1-5 stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Jeffrey Siew can be reached on 571-272-0787.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645